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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,395	01/05/2006	Andres Franco Velasco	3538	1513
278	7590	08/01/2006	EXAMINER	
MICHAEL J. STRIKER 103 EAST NECK ROAD HUNTINGTON, NY 11743				UNDERDAHL, THANE E
		ART UNIT		PAPER NUMBER
		1651		

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/563,395	VELASCO, ANDRES FRANCO	
	Examiner Thane Underdahl	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 1/5/2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 2 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 and 2 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In one instance the applicant uses the terms "materialized", "indistinctly applicable" (claim 1) and "participates" (claim 2)

3. The 112 2<sup>nd</sup> paragraph rejections for claim 1 are described as follows. The term "materialize" is indefinite. Its common use definition is "to make material" or "to cause to be" (see Merriam-Webster OnLine). These definitions are verbs drawn to a method of making but the preamble of the claim is to a composition. Clarification is required.

4. The phrase in claim 1 "A hair regenerator which...being materialized in a mixture of epidermal growth factor, dexpantenol and ..." is indefinite because it is unclear whether the hair regenerator is a separate component of the composition or if it is the composition of the 4 ingredients listed on lines 5 and 7 of claim 1.

5. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process*

*Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

6. The term "indistinctly applicable" in claim 1 is not defined in the specification and is indefinite. These terms are drawn to a method of using yet the preamble of the claim is to a composition. Clarification is required.

7. Also the phrase on line 6 of claim 1 states "that said epidermal growth factor consists of an amniotic-embryonic fluid extract" and is indefinite because it is unclear if the epidermal growth factor (**EGF**) is a protein added to the hair regenerator or if the EGF is inherently contained in the amniotic-embryonic fluid extract (**AFE**) added to the hair regenerator composition. This indefiniteness is compounded in the specification where in line 4-5 of page 2, EGF is a protein expressed recombinantly by *S. cerevisiae*, which contradicts line 27-28 of page 2 where EGF is a protein obtained by simply concentrating AFE from bovines. A person of ordinary skill in the art would recognize that concentrated bovine AFE contains numerous proteins that must be isolated by other means than concentration. The phrase "fifth week of gestation" on line 7 of claim 1 is indefinite as well since it is unclear if it is the EGF or AFE that is removed after five weeks of gestation.

8. Because claim 2 depends from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

9. The 112 2<sup>nd</sup> paragraph rejections for claim 2 are described as follows. The indefiniteness, as described in the rejection of claim 1 concerning the distinctness of

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EGF and AFE also applies to this claim. In this claim it is unclear if the concentration of EGF or AFE should meet the limitation of 300 ng/mL.

10. The terms "injectable regenerator" and "cosmetic regenerator" are not art defined terms and as such are unclear in how they limit the claim. Also there is insufficient antecedent basis for these limitations in the claim.

11. The use of the term "participates" is unclear in its reference to sodium hyaluronate (NaHA) and dexpantenol (dexP). Again the claim is drawn to a composition but the verb "participates" leads it to a method of making. The unit of dexP in the amount of 250 mg is indefinite. It is unclear if that is the total amount of dexP per application of the hair regenerator or the entire amount in the composition. Also the unit of NaHA of 0.20 cm<sup>3</sup> is indefinite. NaHA is a solid salt, not typically characterized by a volume when administering a dose. If the claim is drawn to a solution to NaHA some unit of concentration is necessary.

#### ***Claim Rejections***

12. The following are two separate rejections for the claims 1 and 2 in this specification. These rejections are based on two separate interpretations of the claims. Each rejection states which interpretation they are drawn to. This is done only in the interest of compact prosecution of this application.

#### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

14. A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by

Hersh et al. (U.S. Patent # 6,337,320).

16. These claims are drawn to a hair regenerator composition containing EGF, dexP, and NaHA.

17. The table below diagrams the teachings of Hersh et al. and the claims they are drawn to.

Hersh et al. teach:	Claims	Reference
A composition for a reparative body lotion for chronic skin damage containing NaHA, dexP and EGF	1 and 2	Abstract and Example 4
Composition contains NaHA at 0.16% by wt	1 and 2	Example 4
Composition contains dexP at 0.71% by wt	1 and 2	Example 4
Composition contains EGF at 0.25% by wt	1 and 2	Example 4

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh et al. (U.S. Patent # 6,337,320) as applied to claims 1 and 2 above and in view of Kalopissis et al. (U.S. Patent #3,733,402).

20. These claims read on a hair regenerator comprising AFE, dexP, and NaHA.

21. Hersh et al. teach in Example 4 of their patent a skin reparative composition that contains dexP and NaHA in the amounts listed above. This skin lotion is to assist in repair damaged skin (col 7, Summary of the Invention). Hersh et al. does not teach the use of AFE in a composition specifically for hair regeneration. This is taught by Kalopissis et al.

22. Kalopissis et al. teach the use of cow amniotic liquid (abstract) in a hair regenerative formula that can be combined with a cosmetic composition (col 2, line 11).

23. It would therefore have been obvious for the person of ordinary skill in the art to add cow amniotic liquid to the invention of Hersh et al. The motivation is provided by Kalopissis et al. who desire to put the amniotic liquid in a cosmetic composition such as the ones embodied in the invention of Hersh et al. (col 7, line 28). The reasonable expectation of success is provided by Hersh et al. whose compositions already include other biological extracts such as green tea, carrot oil, and cocoa butter (Example 1, Table). Therefore, the invention as a whole would have been *prima facie* obvious at the time of filing. To the extent that the claims have concentration ranges associated with the components in the composition. Please see M.P.E.P. § 2144.05 IIA. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical (M.P.E.P. § 2144.05 II).

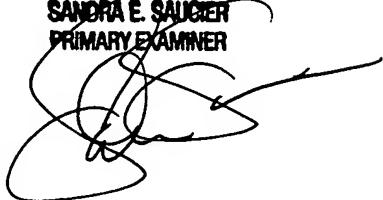
24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is MacDonald Hull et al. (British Journal of Dermatology 149 (2003) 692).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached on 8:00 to 17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Thane Underdahl  
Art Unit 1651

  
SANDRA E. SAIGER  
PRIMARY EXAMINER